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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jichu Yang

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,824	Applicant(s) YANG ET AL.	
	Examiner Taofiq A. Solola	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,2 and 4-10 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 6-9 is/are allowed.
- 6) ☐ Claim(s) 1,2,4,5 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>na</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-2, 4-10 are pending in this application.

Claim 3 is deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. The claim is drawn to treating cardiovascular and cerebrovascular diseases, which are symptoms of hypertension (HTN). Treatment of the symptoms would not alleviate the underlying HTN and therefore redundant. Also, cardiovascular and cerebrovascular diseases embrace many diseases arising from causes outside of HTN. Such are not treatable by the instant compounds. In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). By deleting the claim the rejection would be overcome.

The requirement of 35 USC 112, is not what is known or obvious to one of ordinary skill in the art but a “full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same”, *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). See also the status above.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Varfalvi et al., HU 44495 A2.

Varfalvi et al., disclose compounds and compositions thereof in the attached abstract. See lines 11-12 of the abstract, Wherein R1-R4 are each methyl and R5 is H in formulae I-II.

Claims 1-2, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Rizzo et al., WO 2001/00577 (CN 1356982 A).

Rizzo et al., made compounds of formula I, wherein R is H, C1-C6-alkyl, haloC1-C6-alkyl, phenyl or benzyl, and R1-R6 are each H, C1-C6-alkyl, haloC1-C6-alkyl, phenyl. The compounds of Rizzo et al., have limited number of variations for each substituent, there are no alternative points of attachments of the substituents to the rings and the parent structural nuclei do not change. Therefore, Rizzo “has described to those of ordinary skill in [the] art each of the various permutations involved here as fully as if he had drawn each structural formula or had written each name.” *In re Petering*, 133 USPQ 275 (CCPA 1962), *Bristol-Myers Squibs Co. v. Benvenue Labs. Inc.*, 246 F3d 1368, 1380 (Fed Cir, 2001).

Response to Argument

Applicant's arguments filed 9/11/08 have been fully considered but they are not persuasive. Applicant contends compounds I-II cited at the end of claim 1 are not disclosed by Varfalvi et al. This is not persuasive for reasons set forth above.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over above prior arts.

Applicant claims compounds of formula I and composition thereof. In preferred embodiment the composition is in dosage forms.

Determination of the scope and content of the prior art (MPEP 2141.01)

Varfalvi et al., disclose compounds and compositions thereof as set forth above.

Rizzo et al., disclose compounds as set forth above and their use for making pharmaceuticals or salts thereof.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention (1st compound) and that of Varfalvi et al., is that at position R1, compound II of Varfalvi et al., is 2° amine instead of 3° amine by applicant.

The difference between the instant invention and that of Rizzo et al., is that applicant claims the composition and dosage form instead of their use for making pharmaceuticals or salts thereof by Rizzo et al.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

However, 2° and 3° amines are obvious variants. *Ex parte Bluestone*, 135 USPQ 199 (1961). Further, determining the dose of a compound is well known in the practice of medicine. One of ordinary skill in the art would have known to claim the 3° of a 2° amine and determine the dose of prior arts' compounds at the time the invention was made. The motivation is from

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knowing that 2° and 3° amines are obvious variants, and from the common practice in medicine of using drugs in dosage forms.

Response to Argument

Applicant's arguments filed 9/11/08 have been fully considered but they are not persuasive. Applicant contends instant compounds I-II cited at the end of claim 1 are not disclosed by the prior arts. This is not persuasive for reasons set forth above. Applicant further argues there is no motivation, teaching or suggestion in the prior arts to modify prior arts' compounds. This argument is foreclosed by the recent decision in *KSR Int. Co. v. Teleflex Inc.*, 127 S.Ct, at 1741, 82 USPQ2d 1385 at 1396 (2007). The Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The instant modification is motivated by knowledge generally available to one of ordinary skill in the art as set forth above.

Applicant also contends the instant compounds have different utilities. This is not persuasive absent a showing of unexpected result through side-by-side studies.

Allowable Claims

Claims 6-9 are allowable over prior arts of record.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 9/11/08, prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

November 22, 2008